

### **REMARKS**

The comments of the Examiner as set forth in the official office action of August 13, 2003 have been carefully studied and reviewed. In this response, claim 15 has been canceled without prejudice, claims 11, 12, 13, 14, 24 and 26 have been amended herein, and new claims 29 through 42 have been added. For the reasons set forth above it is respectfully urged that the present application is in condition for allowance and allowance is respectfully requested.

First, the Examiner has rejected claims 11, 13 and 16-22 as being drawn to non-statutory subject matter pursuant to 35 USC §101 because the claimed invention is directed to non-statutory subject matter. Applicant respectfully disagrees. The claims are directed to a method of prescribing and dispensing prescription pharmaceutical products. The claimed invention is well within the bounds of statutory subject matter as articulated in Section 101 and as prescribed in numerous opinions by the courts, particularly the Federal Circuit.

Apparently it is the Examiner's position that the invention of claim 11 fails the statutory subject matter test because the invention is not within the technological arts. In discussing this, it appears that the Examiner's position is that claim 11 is simply directed to an abstract idea and does not apply, involve, use or advance the technological arts.

Claim 11 is far from an abstract idea. Claim 11 includes numerous steps involved in a novel method of prescribing and dispensing pharmaceutical products. The step of forming a pharmaceutical product media and encoding that media with information that identifies one or more particular prescription pharmaceutical products is itself a method step that goes beyond the recitation of a mere idea. However, claim 11 does not stop there. It goes on to recite issuing the pharmaceutical product media to one or more prescribers, such as, for example, doctors. Then the method calls for activating a pharmaceutical product media and transferring the activated pharmaceutical product media from a prescriber to a patient. Finally, the claim

calls for presenting the pharmaceutical product media to a pharmacy that fills the prescription identified by the pharmaceutical product media.

Perhaps the subject matter of claim 11 and its breadth may have inspired this 101 rejection. However, it is well settled that whether claims are directed to subject matter within Section 101 should not turn on whether the claimed subject matter does "business" instead of something else. And, whether a claim is too broad to be patentable is not to be judged under Section 101, but rather under Sections 102, 103 and 112.

In the end, the rejection based on Section 101 appears to be conclusionary and not based on any specific facts that can withstand scrutiny. Claim 11, in terms of patentable subject matter, is no different than other conventional method claims. Accordingly, the Examiner is respectfully urged to withdraw the Section 101 rejections.

Claims 11, 13, 16-25 stand rejected under 35 USC §102 as being anticipated by Lapsker, U.S. Patent No. 4,971,362. In order to anticipate, each and every element and limitation of a claim must be present in a single reference. *In re Bond*, 910 F.2d 831, 832 (Fed. Cir. 1990). That is, the identical invention, as claimed, must be shown in as complete detail as contained in the claims. *Richardson v. Suzuki Motor Co.*, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). Expressed in another way, in order for anticipation to exist, not only must a single reference show each and every limitation of the claim, but the single prior art reference must show the identical invention as precisely described in the claim. Indeed, anticipation requires that the single prior art reference disclose every element and limitation of the claimed invention arranged in the same manner as claimed. *Lindermann Maschinenfabrik v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1458 (Fed. Cir. 1984).

The Lapsker patent is directed to a preprinted paper prescription pad. It appears that the prescription pad includes a preprinted prescription order or description along with a check leaf. The doctor simply signs the preprinted prescription and turns the same over to a patient who then delivers the signed preprinted prescription along with the check to the pharmacy. The

pharmacy fills the prescription and removes the check from the prescription and deposits the check in a deposit account. That is the essence of the Lapsker teaching.

In maintaining that original claim 11 is anticipated by Lapsker, the Examiner has improperly interpreted the activating element of the claim. Basically the Examiner's position is that when the physician in Lapsker signs the preprinted prescription that such constitutes activating as described and set forth in paragraph C of claim 11. That is an unreasonable broad interpretation of the activating step and is inconsistent with the specification and how a person of ordinary skill in the art would construe the term. Notwithstanding, Applicant has amended claim 11 to call for electronically activating the pharmaceutical product media. Clearly Lapsker does not show or teach any electronic communication and certainly does not show electronically activating the pharmaceutical product medium.

In similar fashion, claim 13 has been amended to call for the pharmacy electronically validating the pharmaceutical product media. There is, of course, no electronic validation communication disclosed in the Lapsker patent and indeed the pharmacy, upon receipt of the signed preprinted prescription paper, does not electronically verify anything related to the preprinted prescription. Thus, claim 13 cannot be anticipated.

Claim 12, 14 and 26-28 stand rejected as being unpatentable over Lapsker in view of Edelson. For the reasons set forth below, the Examiner has not made out a prima facie case of obviousness and these claims are allowable.

First, in order to make out a prima facie case of obviousness, the Examiner must meet two requirements. First the primary reference as modified must meet each and every element and limitation of the claim. Secondly, the Examiner must show that there is a legitimate motivation for a person of ordinary skill in the art to combine the teachings of Lapsker and Edelson to form the claimed invention. It goes without saying that the motivation cannot be based on applicant's disclosure and cannot be based on hindsight. In this case, the Examiner's prima facie case of obviousness fails for both reasons.

Claim 12 is as follows:

The method of claim 11, wherein electronically activating the pharmaceutical product media entails a prescriber communicatively linking the pharmaceutical product media to a central computing station where the central computing station records encoded information from the pharmaceutical product media into a database associated with the central computing station.

It is important to appreciate what is claimed in claim 12. The claim clearly calls for activating the pharmaceutical product media. But claim 12 provides a particular way of activating the pharmaceutical product media. It prescribes that the activating step is achieved by a prescriber communicatively linking the pharmaceutical product media to a central computing station. Claim 12 goes further and calls for the central computing station to record encoded information from the pharmaceutical product media into a database associated with a central computing station when the media is activated.

That is not obvious from Lapsker and Edelson. The Examiner finds the activating step to be present in Lapsker due to the doctor simply signing the preprinted prescription form. The doctor, when signing the preprinted prescription form to create what the Examiner maintains as "activating," communicates with no one. He simply signs his name. There is, indeed, no activating communication between the signing doctor and another party, computing station, database, etc.

The Edelson patent as described in prior responses, is simply a computerized database that assists physicians in prescribing the right pharmaceutical product and the appropriate dosage for a certain diagnosis. The important point here is that there is no activating step in the Edelson system. While it is true that the Edelson disclosure includes an electronic database and the ability of the doctor and pharmacist to gain access to that database, Edelson has nothing whatsoever to do with activating a pharmaceutical product media of the type set forth in the claims of this case. Given the fact that Edelson does not entail activating or validating a pharmaceutical product media and that the so-called activating and validating that takes place in

Lapsker is simply the recognition that a prescription pad has been signed, it is difficult to appreciate how the claimed invention of claim 12, for example, is made obvious. The claimed invention is not about electronically communicating a prescriber's signature to a database or to the pharmacy for that matter. Activating, as called for in claim 12, calls for communicatively linking the pharmaceutical product media to a central computing station and for the central computing station to record encoded information from the pharmaceutical product media. That does not happen in Lapsker or Edelson, and moreover, that method step cannot even be created from the combined teachings because the claimed step is foreign to the teachings of Lapsker, Edelson or any obvious combination thereof.

Further, claim 12 calls for the encoded information on the pharmaceutical product media to be recorded in the database when the pharmaceutical product media is electronically activated. The Examiner does not even maintain that this is taught by either Lapsker or Edelson. Indeed, the Examiner acknowledges that it is not taught by Lapsker. Nowhere in the office action does the Examiner maintain that Edelson records information from the pharmaceutical product media in a database in response to the pharmaceutical product media being electronically activated. For this reason also, the Examiner has not made out a prima facie case of obviousness.

The very same argument applies to claim 14. Applicant will not repeat the argument, but again it is basically the same. There is no validation by the pharmacy communicatively linking the pharmaceutical product media with the central computer station to determine if the pharmaceutical product media has previously been activated.

Therefore, even if there was an appropriate motivation to combine, the Lapsker patent, as modified by the Examiner, would still not meet each and every element and limitation of the claimed invention.

Moreover, the motivation proffered by the Examiner is inadequate in this case. The Examiner notes that:

As suggested by Edelson, one would have been motivated to do this to minimize prescription fraud and system abuse.

(Col. 27, lines 30-43).

This is precisely one of the impetuses that spurred the Applicant to invent the present invention. It is fundamental that in a 103 analysis, the Patent Office cannot use what the teacher taught against the teacher. For that reason alone the motivation is legally wrong and insufficient.

Further, the beauty of the Lapsker invention is that it is a paper system - easy to use and quite economical - and does not require the pharmacist and the doctors to purchase and implement expensive computerized systems. Indeed the entire thrust of the Lapsker patent is built around the preprinted prescription paper pad and check. Indeed this is an object of the invention:

It is a further object of the invention to provide a prescription pad assembly.....

Lapsker, col. 2, lines 57-58.

It is a further object of the invention to provide a prescription pad assembly and a binder assembly incorporating the prescription pad assembly.

Lapsker, col. 2, lines 61-63.

Thus, the proffered motivation teaches a way from the very essence of the primary reference. Turning the paper prescription pad into a computerized system including databases, hardware and communication links destroys the essence of the Lapsker invention. A person of ordinary skill in the art appreciating the essence of Lapsker would never be motivated to make the modifications proffered by the Examiner.

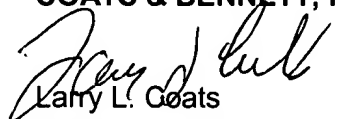
The Examiner's attention is directed to new claim 32. New claim 32 is a rewrite of claim 15 which the Examiner has indicated is in condition for allowance.

For the foregoing reasons, it is respectfully urged that all of the claims of the present application are in condition for allowance and allowance is respectfully requested.

Respectfully submitted,

By:

**COATS & BENNETT, P.L.L.C.**

  
Larry L. Coats  
Registration No. 25,620

P.O. Box 5  
Raleigh, NC 27602  
Telephone: (919) 854-1844

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